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10/801,078	03/15/2004	Krzysztof Palczewski	0069509-000003	9475	
21839 7590 12/10/2007 BUCHANAN INGERSOLL & ROONEY PC			EXAMINER		
10/801,078 03/15/2004 Krzysztof Palczewski	HUANG, GIGI GEORGIANA				
ALEXANDRIA	A, VA 22313-1404		ART UNIT PAPER NUMBER		
			1618	-	
			NOTIFICATION DATE	DELIVERY MODE	
			12/10/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com debra.hawkins@bipc.com

•	A	pplication No.	Applicant(s)			
		10/801,078	PALCZEWSKI ET	PALCZEWSKI ET AL.		
Office Action Summa	L	xaminer	Art Unit			
	10	iGi Huang	1618			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PER WHICHEVER IS LONGER, FROM 7 - Extensions of time may be available under the p after SIX (6) MONTHS from the mailing date of t - If NO period for reply is specified above, the may - Failure to reply within the set or extended period Any reply received by the Office later than three earned patent term adjustment. See 37 CFR 1.7	THE MAILING DAT rovisions of 37 CFR 1.136(anis communication. cimum statutory period will a for reply will, by statute, camonths after the mailing da	E OF THIS COMMUNICA a). In no event, however, may a reply apply and will expire SIX (6) MONTH: use the application to become ABAN	TION. be timely filed from the mailing date of this condition S from the Mailing date of this condition S J. S. C. § 133).			
Status						
1) Responsive to communication	(s) filed on <u>15 Mar</u>	<u>ch 2004</u> .				
2a) ☐ This action is FINAL.	· —					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-34 is/are pending i 4a) Of the above claim(s) 5) Claim(s) is/are allowed 6) Claim(s) is/are rejected 7) Claim(s) is/are objected 8) Claim(s) 1-34 are subject to re	is/are withdrawn d. d to.		•			
Application Papers						
9) The specification is objected to 10) The drawing(s) filed on Applicant may not request that as Replacement drawing sheet(s) in 11) The oath or declaration is objective.	is/are: a) accep ny objection to the dra cluding the correction	awing(s) be held in abeyance is required if the drawing(s)	e. See 37 CFR 1.85(a). is objected to. See 37 C			
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)		_				
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing R Information Disclosure Statement(s) (PTO-Paper No(s)/Mail Date		Paper No(s)/l	nmary (PTO-413) Mail Date irmal Patent Application			

DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-9, drawn to a method of restoring photoreceptor function in a vertebrate eye by administering a synthetic retinoid.
 - II. Claims 10-15, drawn to a method for stabilizing mutant opsin protein.
- III. Claims 16-22, drawn to a method of ameliorating loss of photoreceptor function in a vertebrate eye by administering a synthetic retinoid.
- IV. Claims 23-26, drawn to an ophthalmologic composition comprising a synthetic retinoid.
- V. Claims 27-30, drawn to an oral dosage form comprising a synthetic retinoid.
 - VI. Claims 31-34, drawn to a method of identifying an opsin-binding synthetic retinoid to stabilize a mutant opsin protein.

The inventions are distinct, each from the other because of the following reasons:

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

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- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. If Group I is elected the following species election applies:

This application contains claims directed to the following patentably distinct species of retinoid and method of administration:

a. Methods of administration: local (eye drops/topical, injection - intraocular or periocular) or oral.

Applicant is required, in reply to this action, to elect a local or oral mode of administration. If a local method of administration is elected, a specific method (eye drops/topical, injection - intraocular or periocular) is to be elected for examination.

- b. Species of retinoid:
 - 1) Synthetic retinoid of formula I
 - 2) Synthetic retinoid of formula II
 - 3) Synthetic retinoid of formula III
 - 4) Synthetic retinoid of formula IV
 - 5) Synthetic retinoid of formula V

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- 6) Synthetic retinoid of formula VI
- 7) Synthetic retinoid of formula VII
- 8) Synthetic retinoid of formula VIII
- 9) Synthetic retinoid of formula IX
- 10) Synthetic retinoid of formula X
- 11) Synthetic retinoid of formula XI
- 12) Synthetic retinoid of formula XII
- 13) Synthetic retinoid of formula XIII
- 14) 11-*cis*-7-ring retinal
- 15) 9-*cis*-7-ring retinal
- 16) cycloheptatrienylidene 11-cis-locked retinal
- 17) cycloheptatrienylidene 9-cis-locked retinal
- 18) 9-*cis*-fused retinal
- 19) All other retinoids not listed above

The species include all possible retinoids stated in the claims.

The species disclosed in each group contains many species of retinoids several of which have multiple uses and some with no applicable or divergent function.

Applicant is required, in reply to this action, to elect a single species group and from that species group (which can be a genus of compounds), elect a specific *single* compound with both the *name* and the *structure* of the compound for examination.

The claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any

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claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly

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and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

3. If Group II is elected the following species election applies:

This application contains claims directed to the following patentably distinct species of retinoid:

- a. Species of retinoid:
 - 1) Synthetic retinoid of formula I
 - 2) Synthetic retinoid of formula II
 - 3) Synthetic retinoid of formula III

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- Synthetic retinoid of formula IV
- 5) Synthetic retinoid of formula V
- 6) Synthetic retinoid of formula VI
- 7) Synthetic retinoid of formula VII
- 8) Synthetic retinoid of formula VIII
- 9) Synthetic retinoid of formula IX
- 10) Synthetic retinoid of formula X
- 11) Synthetic retinoid of formula XI
- 12) Synthetic retinoid of formula XII
- 13) Synthetic retinoid of formula XIII
- 14) 11-*cis*-7-ring retinal
- 15) 9-*cis*-7-ring retinal
- 16) cycloheptatrienylidene 11-cis-locked retinal
- 17) cycloheptatrienylidene 9-cis-locked retinal
- 18) 11-*cis*-locked retinal
- 19) 9-cis-locked retinal
- 20) All other retinoids not listed above

The species include all possible retinoids stated in the claims.

The species disclosed in each group contains many species of retinoids several of which have multiple uses and some with no applicable or divergent function.

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Applicant is required, in reply to this action, to elect a single species group and from that species group (which can be a genus of compounds), elect a specific *single* compound with both the *name* and the *structure* of the compound for examination.

The claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 10 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing

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the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

4. If Group III is elected the following species election applies:

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This application contains claims directed to the following patentably distinct species of retinoid and method of administration:

a. Methods of administration: local or oral.

Applicant is required, in reply to this action, to elect a local or oral mode of administration for examination.

- b. Species of retinoid:
 - 1) Synthetic retinoid of formula I
 - 2) Synthetic retinoid of formula II
 - 3) Synthetic retinoid of formula III
 - 4) Synthetic retinoid of formula IV
 - 5) Synthetic retinoid of formula V
 - 6) Synthetic retinoid of formula VI
 - 7) Synthetic retinoid of formula VII
 - 8) Synthetic retinoid of formula VIII
 - 9) Synthetic retinoid of formula IX
 - 10) Synthetic retinoid of formula X
 - 11) Synthetic retinoid of formula XI
 - 12) Synthetic retinoid of formula XII
 - 13) Synthetic retinoid of formula XIII
 - 14) 11-*cis*-7-ring retinal
 - 15) 9-cis-7-ring retinal
 - 16) cycloheptatrienylidene 11-cis-locked retinal

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- 17) cycloheptatrienylidene 9-cis-locked retinal
- 18) All other retinoids not listed above

The species include all possible retinoids stated in the claims.

The species disclosed in each group contains many species of retinoids several of which have multiple uses and some with no applicable or divergent function.

Applicant is required, in reply to this action, to elect a single species group and from that species group (which can be a genus of compounds), elect a specific *single* compound with both the *name* and the *structure* of the compound for examination.

The claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 16 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

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not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. If Group IV is elected the following species election applies:

This application contains claims directed to the following patentably distinct species of retinoid and method of administration:

- a. Species of retinoid:
 - 1) Synthetic retinoid of formula I
 - 2) Synthetic retinoid of formula II
 - 3) Synthetic retinoid of formula III
 - 4) Synthetic retinoid of formula IV
 - 5) Synthetic retinoid of formula V
 - 6) Synthetic retinoid of formula VI
 - 7) Synthetic retinoid of formula VII
 - 8) Synthetic retinoid of formula VIII
 - 9) Synthetic retinoid of formula IX
 - 10) Synthetic retinoid of formula X
 - 11) Synthetic retinoid of formula XI
 - 12) Synthetic retinoid of formula XII
 - 13) Synthetic retinoid of formula XIII
 - 14) 11-*cis*-7-ring retinal
 - 15) 9-*cis*-7-ring retinal

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- 16) cycloheptatrienylidene 11-cis-locked retinal
- 17) cycloheptatrienylidene 9-cis-locked retinal
- 18) All other retinoids not listed above

The species include all possible retinoids stated in the claims.

The species disclosed in each group contains many species of retinoids several of which have multiple uses and some with no applicable or divergent function.

Applicant is required, in reply to this action, to elect a single species group and from that species group (which can be a genus of compounds), elect a specific *single* compound with both the *name* and the *structure* of the compound for examination.

The claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 27 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or

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employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

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prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. If Group V is elected the following species election applies:

This application contains claims directed to the following patentably distinct species of retinoid and method of administration:

- a. Species of retinoid:
 - 1) Synthetic retinoid of formula I
 - 2) Synthetic retinoid of formula II
 - 3) Synthetic retinoid of formula III
 - 4) Synthetic retinoid of formula IV
 - 5) Synthetic retinoid of formula V
 - 6) Synthetic retinoid of formula VI
 - 7) Synthetic retinoid of formula VII
 - 8) Synthetic retinoid of formula VIII
 - 9) Synthetic retinoid of formula IX
 - 10) Synthetic retinoid of formula X
 - 11) Synthetic retinoid of formula XI
 - 12) Synthetic retinoid of formula XII
 - 13) Synthetic retinoid of formula XIII

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. 14) All other retinoids not listed above

The species include all possible retinoids stated in the claims.

The species disclosed in each group contains many species of retinoids several of which have multiple uses and some with no applicable or divergent function.

Applicant is required, in reply to this action, to elect a single species group and from that species group (which can be a genus of compounds), elect a specific *single* compound with both the *name* and the *structure* of the compound for examination.

The claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 31 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

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not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Zohreh Fay (Primary Examiner)